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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/813,408	03/21/2001	Simon Delagrave	HER-0041	2931

7590 03/27/2003

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EXAMINER
TRAN, MY CHAU T

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 03/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/813,408	Applicant(s) DELAGRAVE ET AL.	
	Examiner My-Chau T. Tran	Art Unit 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 January 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-56* is/are pending in the application.

4a) Of the above claim(s) *10-56* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 March 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5-6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's amendment filed 1/13/03 in Paper No. 8 is acknowledged and entered. Claim 23 is amended. Claims 10-56 have been withdrawn from further consideration a being drawn to a non-elected invention. Claims 1-56 are pending.

Election/Restrictions

2. Applicant's election with traverse of Group I (Claims 1-9) in Paper No. 8 is acknowledged. The traversal is on the ground(s) that Groups III (Claims 11-22) and Group IV (Claims 23-25) should be joined with Group I for the claims grouped separately are not independent and distinct and therefore, the examination of Group I, Group III, and Group IV cannot constitute a serious burden because they encompassed methods involving coupling of oligonucleotides. These arguments have been fully considered but are not found to be persuasive for the reasons below.

First, the classification system has no statutory recognition whether inventions are independent and distinct. For example, each class and subclass is comprised of numerous completely independent and distinct inventions.

Second, MPEP 803 states that restriction is proper between patentably distinct inventions where the inventions are (1) independent **or** distinct as claimed and (2) a serious search and examination burden is placed on the examiner if restriction is not required.

The term "distinct" is defined to mean that two or more subjects as disclosed are related, for example, as product and method of use, but are capable of separate manufacture, use or sale as claimed, and are patentable over each other (see MPEP 802.1). In the instant situation, the

inventions of Group I, Group III, and Group IV are drawn to distinct inventions, which are related as separate methods capable of different method steps that have different functions and modes of operation. Restrictions between the inventions are deemed to be proper for the reason previously set forth.

In regard to burden of search and examination, MPEP 803 states that a burden can be shown if the examiner shows either separate classification, different field of search or separate status in the art. Group I (Claims 1-9) is classified in class 435, subclass 6, Group III (Claims 11-22) is classified in class 435, subclass 4, and Group IV (Claims 23-25) is classified in class 536, subclass 25.3. In the instant case a burden has been established in showing that the inventions of Group I, Group III, and Group IV are classified separately necessitating different searches of issued US Patents in different (classes and/or subclasses). However, classification of subject matter is merely one indication of the burdensome nature of search. The literature search, particularly relevant in this art, is not co-extensive, because for example a patentability determination for Group III would involve a determination of the patentability of the method step of blocking the 3' end of the oligonucleotides with a blocking group to form a plurality of blocked oligonucleotides while a patentability determination for Group I would involve a consideration of the patentability of method step of coupling the oligonucleotides to form a plurality of coupled oligonucleotides. Further, the methods involving coupling of oligonucleotides would encompasses such method as hybridization (coupling oligonucleotides to form double stranded DNA), or the method of attaching (coupling) oligonucleotides on a support to form an array. Each of these different methods has different methods steps that are different in requiring different reagents and/or producing different results. Additionally, it is submitted

that the inventions of Group I, Group III, and Group IV have acquired a separate status in the art. Clearly different searches and issues are involved in the examination of each Group.

For these reasons, the restriction requirement is deemed to be proper and is therefore made **FINAL**.

3. However, if applicant believes that the method of claim 1 is the same as the method of claims 11 and 23 then applicant should add the limitation of the methods steps in claims 11 and 23 to claim 1. If applicant amend claim 1 to include the limitation of claims 11 and 23 then Groups III and IV will be rejoined with Group I.

4. Claims 10-56 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8.

Specification

5. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code such as pg. 19 (line 30), pg. 20 (line 23), pg. 21 (line 4 and 21), pg. 35 (line 7) and others throughout the specification. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

6. Claims 1-9 are treated on the merit in this Office Action.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 1 recites coupling the oligonucleotides to form a plurality of coupled oligonucleotides. This is vague and indefinite because it is unclear to what type of "coupling" this method step is referring to (e.g. extension of oligonucleotides, hybridization, or attachment to a solid support) or at which ends of the oligonucleotide is the "coupling" occurring (e.g. 3′ ends or 5′ ends).

b. Claim 1 recites each of the coupled oligonucleotides represents a region of the polynucleotide. This is vague and indefinite because it is unclear to what "a region of the polynucleotide" is the coupled oligonucleotides referring to (e.g. the sequence of the region, its length or size).

c. Claim 1 recites each of the coupled oligonucleotides shares at least one terminal region of sequence with at least one other oligonucleotide. This is vague and indefinite because it is unclear to what "terminal region of sequence" is the coupled oligonucleotides referring to (e.g. the type sequence, its length or size, the 3′ terminal ends or 5′ terminal ends).

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 1-2, 4-6, and 8-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Barany et al. (US Patent 6,506,594 B1).

"The presently claimed invention recites a method of preparing a polynucleotide having a target sequence from a plurality of oligonucleotides. The method comprise of coupling the oligonucleotides to form a plurality of coupled oligonucleotides, and assembling the polynucleotide by extension of the coupled oligonucleotides. The coupling method step comprise of ligating the oligonucleotides with ligase. The oligonucleotides are amplified prior to assembling the polynucleotide. The method further comprise of attaching the oligonucleotides to a solid support."

Barany et al. disclose a method for identifying one or more of a plurality of sequences in a plurality of target nucleotide sequences. The method comprise of a ligation phase, a capture phase, and a detection phase (Abstract; col. 5, lines 25-30). The ligation phase comprise of a plurality of oligonucleotides sets wherein each set includes a first oligonucleotide probe, having a target-specific portion and an addressable array-specific portion, and a second oligonucleotide probe, having a target-specific portion and a detectable reporter label (col. 5, lines 33-41). The

first and second oligonucleotide probes in a particular set are suitable for ligation together when hybridized adjacent to one another on a corresponding target nucleotide sequence. Prior to the ligation detection reaction phase the sample is preferably amplified by PCR (col. 14, lines 13-15; col. 14, lines 38-67 to col. 15, lines 1-4). The method further comprise of forming an array of oligonucleotides on a solid support (col. 6, lines 18-29). Therefore, the method of Barany et al. anticipates the presently claimed invention.

11. Claims 1-2, and 4-5 are rejected under 35 U.S.C. 102(e) as being anticipated by Harney (Us Patent 6,495,318 B2).

"The presently claimed invention recites a method of preparing a polynucleotide having a target sequence from a plurality of oligonucleotides. The method comprise of coupling the oligonucleotides to form a plurality of coupled oligonucleotides, and assembling the polynucleotide by extension of the coupled oligonucleotides. The coupling method step comprise of ligating the oligonucleotides with ligase. The method further comprise of attaching the oligonucleotides to a solid support."

Harney disclosed a method of solid phase synthesis wherein the nucleic acid components (oligonucleotides) can be linked sequentially to form the nucleic acid construct (polynucleotides) (col. 28, lines 4-26). The method comprise of attachment to a solid support as a starting point in the assembly of a series of nucleic acid components, in a defined order, to form a multicomponent nucleic acid construct. The initial nucleic acid component is attached to a solid support. Additional nucleic acid components, designed to contain unique terminal sequences at either end, are added in a step-wise fashion, as single components or non-functional

multicomponent constructs, and the assembly of components is based on the specific annealing of complementary terminal sequence pairs. Nucleic acid components may be ligated together, using a ligase enzyme, after each nucleic acid component addition step in the assembly of the larger construct. Therefore, the method of Harney anticipates the claimed invention.

12. Claims 1, 4-5, and 7-8 are rejected under 35 U.S.C. 102(e) as being anticipated by Huang et al. (US Patent 6,489,466 B2).

"The presently claimed invention recites a method of preparing a polynucleotide having a target sequence from a plurality of oligonucleotides. The method comprise of coupling the oligonucleotides to form a plurality of coupled oligonucleotides, and assembling the polynucleotide by extension of the coupled oligonucleotides. The coupling method step comprise of blocking one end of at least one of the oligonucleotides prior to coupling. The method further comprise of attaching the oligonucleotides to a solid support."

Huang et al. disclosed a method of immobilizing oligonucleotide to a substrate (solid support) (col. 1, lines 37-40). The method comprises of a method for an oligonucleotide synthesis (col. 2, lines 17-35). The method covers a deprotection-activation-coupling oligonucleotide synthesis which consists of a nucleotide or an oligonucleotide having a free terminal C-3' hydroxyl and a terminal C-5' that is blocked by a group, wherein the free terminal C-3' hydroxyl is activated with a phosphorous activating group. Therefore, the method of Huang et al. anticipates the presently claimed invention.

13. Claims 1-5, and 7-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Delagrave (US Patent 6,479,262 B1).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

"The presently claimed invention recites a method of preparing a polynucleotide having a target sequence from a plurality of oligonucleotides. The method comprise of coupling the oligonucleotides to form a plurality of coupled oligonucleotides, and assembling the polynucleotide by extension of the coupled oligonucleotides. The coupling method step comprise of ligating the oligonucleotides with ligase and wherein at least one of the oligonucleotide of the coupled oligonucleotide is blocked at one end prior to the coupling. The ligase is T4 RNA ligase. The method further comprise of attaching the oligonucleotides to a solid support."

Delagrave disclosed a method of preparing polynucleotides on a solid support wherein the polynucleotides are assembled in either direction (e.g. 5′to 3′ or 3′ to 5′) by ligating a plurality of oligonucleotides (Abstract; col. 3, lines 8-35). The method comprise of contacting the solid support with an oligonucleotide from a plurality of oligonucleotides to form a tethered oligonucleotide (col. 5, lines 38-46; col. 8, lines 15-21). The tethered oligonucleotide is ligated with T4 RNA ligase to another oligonucleotide thereby assembling the polynucleotide (col. 6, lines 30-49). To avoid excessive accumulation of failed sequences, a capping step is performed

(col. 7, lines 26-42; col. 8, lines 61-66). Therefore, the method of Delagrave anticipates the presently claimed invention.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. Claims 1-6, and 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barany et al. (US Patent 6,506,594 B1) in view of Walker et al. (*PNAS*, **1975**, 72(1):122-126).

"The presently claimed invention recites a method of preparing a polynucleotide having a target sequence from a plurality of oligonucleotides. The method comprise of coupling the oligonucleotides to form a plurality of coupled oligonucleotides, and assembling the polynucleotide by extension of the coupled oligonucleotides. The coupling method step comprise

of ligating the oligonucleotides with ligase wherein the ligase is T4 RNA ligase. The oligonucleotides are amplified prior to assembling the polynucleotide. The method further comprise of attaching the oligonucleotides to a solid support."

Barany et al. disclose a method for identifying one or more of a plurality of sequences in a plurality of target nucleotide sequences. The method comprise of a ligation phase, a capture phase, and a detection phase (Abstract; col. 5, lines 25-30). The ligation phase comprise of a plurality of oligonucleotides sets wherein each set includes a first oligonucleotide probe, having a target-specific portion and an addressable array-specific portion, and a second oligonucleotide probe, having a target-specific portion and a detectable reporter label (col. 5, lines 33-41). The first and second oligonucleotide probes in a particular set are suitable for ligation together when hybridized adjacent to one another on a corresponding target nucleotide sequence. Prior to the ligation detection reaction phase the sample is preferably amplified by PCR (col. 14, lines 13-15; col. 14, lines 38-67 to col. 15, lines 1-4). The method further comprise of forming an array of oligonucleotides on a solid support (col. 6, lines 18-29).

The method of Barany et al. does not expressly disclose that the ligase is T4 RNA ligase.

Walker et al. disclosed a method of joining single-stranded oligonucleotides using T4 RNA ligase (Abstract). The RNA ligase has the advantage of not requiring the complementary strand, thereby simplifying the synthetic task (pg. 126, right col., lines 1-2).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include the T4 RNA ligase as taught by Walker et al. in the method of Barany et al. One of ordinary skill in the art would have been motivated to include the T4 RNA ligase in the method of Barany et al. for the advantage of not requiring the complementary

strand, thereby simplifying the synthetic task (Walker: pg. 126, right col., lines 1-2). Since both Barany et al. and Walker et al. disclose a method of coupling oligonucleotides by the method of ligation (Barany: col. 5, lines 33-41; Walker: Abstract).

17. Claims 1, and 4-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huang et al. (US Patent 6,489,466 B2) in view of Harney (Us Patent 6,495,318 B2).

"The presently claimed invention recites a method of preparing a polynucleotide having a target sequence from a plurality of oligonucleotides. The method comprise of coupling the oligonucleotides to form a plurality of coupled oligonucleotides, and assembling the polynucleotide by extension of the coupled oligonucleotides. The coupling method step comprise of blocking one end of at least one of the oligonucleotides prior to coupling. The oligonucleotides are amplified prior to assembling the polynucleotide. The method further comprise of attaching the oligonucleotides to a solid support."

Huang et al. disclosed a method of immobilizing oligonucleotide to a substrate (solid support) (col. 1, lines 37-40). The method comprise of deprotection-activation-coupling oligonucleotide synthesis wherein one end to the oligonucleotide is block (col. 2, lines 17-35).

The method of Huang et al. does not expressly disclose that a method step of amplification of the coupled oligonucleotide.

Harney disclosed a method of solid phase synthesis wherein the nucleic acid components (oligonucleotides) can be linked sequentially to form the nucleic acid construct (polynucleotides) (col. 28, lines 4-26). The method comprise of attachment to a solid support as a starting point in the assembly of a series of nucleic acid components, in a defined order, to form a

multicomponent nucleic acid construct. The initial nucleic acid component is attached to a solid support. Additional nucleic acid components, designed to contain unique terminal sequences at either end, are added in a step-wise fashion, as single components or non-functional multicomponent constructs, and the assembly of components is based on the specific annealing of complementary terminal sequence pairs. Nucleic acid components may be ligated together, using a ligase enzyme, after each nucleic acid component addition step in the assembly of the larger construct. The method further comprise of the method of PCR amplification (col. 13, lines 51-61). The method provides a rapid construction of customized constructs without the need to use restriction enzymes (col. 4, lines 5-8).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a method step of amplification of the coupled oligonucleotide as taught by Harney in the method of Huang et al. One of ordinary skill in the art would have been motivated to include a method step of amplification of the coupled oligonucleotide in the method of Huang et al. for the advantage of providing a rapid construction of customized constructs without the need to use restriction enzymes (Harney: col. 4, lines 5-8). Since both Huang et al. and Harney disclose a method of immobilizing oligonucleotides to a substrate wherein the oligonucleotides are constructs of nucleic acid components (Huang: col. 1, lines 37-40; Harney: col. 28, lines 4-11).

Double Patenting

18. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

19. Claims 1-5, and 7-8 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 7, 10, 12, 14, 18, and 24-26 of U.S. Patent No. 6,479,262 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the presently claimed invention, which is a method of preparing a polynucleotide having a target sequence from a plurality of oligonucleotides. The method comprise of coupling the oligonucleotides to form a plurality of coupled oligonucleotides, and assembling the polynucleotide by extension of the coupled oligonucleotides, would encompass that of the claimed invention of US Patent 6,479,262 B1, which is a method of preparing a polynucleotide having at least 200 nucleotides and a predetermined nucleotide sequence. The method step comprises contacting said solid support with the 3′ terminus of a fist oligonucleotide from said plurality of oligonucleotides to form a tethered oligonucleotide, ligating the 3′ terminus of another oligonucleotide from said plurality of oligonucleotides to the 5′ terminus of the tethered oligonucleotide, phosphorylating the 5′ terminus of said another oligonucleotide, and repeating the steps of ligation and phosphorylation until said polynucleotide is prepared.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999. The examiner is on ***Increased Flex Schedule*** and can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 703-306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

mct
March 24, 2003

PADMASHRI PONNALURI
PRIMARY EXAMINER